



02-13-02

EXPRESS MAIL CERTIFICATE

Date 2/11/02 Label No. 84039137265-45

I hereby certify that, on the date indicated above, this paper or fee was deposited with the U.S. Postal Service & that it was addressed for delivery to the Assistant Commissioner for Patents, Washington, DC 20231 by "Express Mail Post Office to Addressee" service.

Name (Print) B.W. LEESignature B.W. Lee

PLEASE CHARGE ANY DEFICIENCY UP TO \$300.00 OR
CREDIT ANY EXCESS IN THE FEES DUE WITH THIS
DOCUMENT TO OUR DEPOSIT ACCOUNT NO. 04-07100

TECH CENTER 1600/2900
NOV 2 2002RECEIVED
TECH CENTER 1600/2900
FEB 1 9 2002RECEIVED
FEB 1 9 2002

Customer No.:



07278

PATENT TRADEMARK OFFICE

Docket No.: 3272/1H629US2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Maria-Grazia ASCENZI

Serial No.: 09/981,684

Confirmation No.: 6620

Filed: October 17, 2001

For: SYSTEM AND METHOD FOR MODELING BONE STRUCTURE

RECEIVED

NOV 1 9 2002

Technology Center 2100

INFORMATION DISCLOSURE STATEMENT

Hon. Commissioner of
Patents and Trademarks
Washington, DC 20231

Sir:

In order to comply with 37 CFR 1.97 and 1.98, attached hereto is a
copy of Form PTO-1449 and copies of the documents listed thereon.

In accordance with MPEP Sections 609 and 707.05(b), it is requested

RECEIVED
OCT 15 2002
TC 3700 MAIL ROOM

that each document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing Form PTO-1449 next to the document. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

A concise explanation of the relevance of the foreign language documents as required by 37 CFR 1.98 is attached. On information and belief, this concise explanation is from the point of view of that person identified in 37 CFR 1.56 who is most familiar with the subject matter.

The present Information Disclosure Statement is being submitted in compliance with 37 CFR 1.56, but the citation of such document is not to be construed as an admission that such document is necessarily relevant or prior art. No representation is intended that the cited documents represent the results of a complete search, and it is anticipated that the Examiner, in the normal course of examination, will make an independent search and will determine the best prior art consistent with 37 CFR 1.104(a) and 1.106(b) and, in the course of each search, will review for relevance every document cited on the attached form even if not

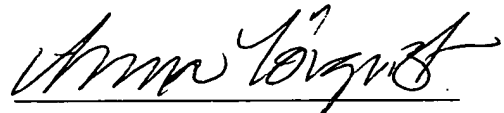
initialed.

Since this submission is being filed before a first office action on the merits, it is believed that no fee is due. However, if the Commissioner determines that a fee is due, the Commissioner is hereby authorized to charge the above deposit account for any deficiency.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,

Dated: February 10, 2002

A handwritten signature in dark ink, appearing to read 'Anna Lövgqvist', is written over a horizontal line.

Anna Lövgqvist, Ph.D.
Limited Recognition Under
37 C.F.R. §10.9(b) (see enclosure)
Representative for Applicant(s)

DARBY & DARBY
805 Third Avenue
New York, NY 10022
(212) 527-7700

EXPRESS MAIL CERTIFICATE

Date 2/11/02 Label No. 39137265-US

I hereby certify that, on the date indicated above, this paper or fee was deposited with the U.S. Postal Service & that it was addressed for delivery to the Assistant Commissioner for Patents, Washington, DC 20231 by "Express Mail Post Office to Addressee" service.

B.W. LEE B.W. Lee
Name (Print) Signature

PLEASE CHARGE ANY DEFICIENCY UP TO \$300.00 OR
CREDIT ANY EXCESS IN THE FEES DUE WITH THIS
DOCUMENT TO OUR DEPOSIT ACCOUNT NO. 04-0100

Customer No.:



07278

PATENT TRADEMARK OFFICE

Docket No.: 3272/1H629US2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Maria-Grazia ASCENZI

Serial No.: 09/981,684

Confirmation No.: 6620

Filed: October 17, 2001

For: SYSTEM AND METHOD FOR MODELING BONE STRUCTURE

RECEIVED
OCT 15 2002
TC 3100 MAIL ROOM

CONCISE EXPLANATION OF FOREIGN LANGUAGE REFERENCE
UNDER 37 C.F.R. 1.98(a)(3)

Hon. Commissioner of
Patents and Trademarks
Washington, DC 20231

Sir:

The accompanying Information Disclosure Statement includes a reference by Gebhardt (Arch. Entwickl. Mech Org., 1905; 20:187-3220; Ref. No. 39 in the PTO-1449 form)("Gephardt"). Since Gephardt is in German, a concise explanation of the

relevance of this foreign language document from the point of view of that person identified in 37 CFR 1.56 who is most familiar with the subject matter is provided.

Gephardt hypothesized that the areas that appear dark on the long bone shaft transverse sections under polarizing light consists of collagen bundles parallel to the bone axis and the axis of the microscope, and that the areas that appear light consists of collagen bundles perpendicular to the bone axis and to the axis of the microscope.

Respectfully submitted,

Dated: February 10, 2002



Anna Löqvist, Ph.D.
Limited Recognition Under
37 C.F.R. §10.9(b) (see enclosure)
Representative for Applicant(s)

DARBY & DARBY
805 Third Avenue
New York, NY 10022
(212) 527-7700




**BEFORE THE OFFICE OF ENROLLMENT AND DISCIPLINE
UNITED STATES PATENT AND TRADEMARK OFFICE**

LIMITED RECOGNITION UNDER 37 CFR § 10.9(b)

Anna Lovqvist is hereby given limited recognition under 37 CFR § 10.9(b) as an employee of the Darby & Darby, PC law firm to prepare and prosecute patent applications wherein the patent applicant is the client of the Darby & Darby, PC law firm, and the attorney or agent of record in the applications is a registered practitioner who is a member of the Darby & Darby, PC law firm. This limited recognition shall expire on the date appearing below, or when whichever of the following events first occurs prior to the date appearing below: (i) Anna Lovqvist ceases to lawfully reside in the United States, (ii) Anna Lovqvist's employment with the Darby & Darby, PC law firm ceases or is terminated, or (iii) Anna Lovqvist ceases to remain or reside in the United States on an H-1 visa.

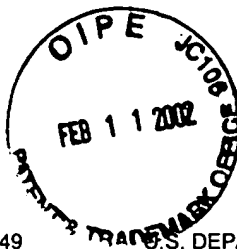
This document constitutes proof of such recognition. The original of this document is on file in the Office of Enrollment and Discipline of the United States Patent and Trademark Office.

Expires: July 12, 2002



Harry I. Moatz
Director of Enrollment and Discipline

RECEIVED
OCT 15 2002
TC 3700 MAIL ROOM



FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE

RECEIVED
NOV 20 2002
SHEET 1 OF 9
TELECENTER 1600/2900

LIST OF REFERENCES CITED BY APPLICANT

(Use Several Sheets if Necessary)

DOCKET NO.: 3272/1H629US2 SERIAL NO: 09/981,684
APPLICANT: ASCENZI, Maria-Grazia FILING DATE: October 17, 2001
CONFIRMATION NO: 6620

U.S. PATENT DOCUMENTS

<u>*EXAMINER INITIALS</u>	<u>DOCUMENT NUMBER</u>	<u>DATE</u>	<u>NAME</u>	<u>CLASS</u>	<u>SUBCLASS</u>	<u>FILING DATE</u>
-------------------------------	----------------------------	-------------	-------------	--------------	-----------------	--------------------

FOREIGN PATENT DOCUMENTS

<u>*EXAMINER INITIALS</u>	<u>DOCUMENT NUMBER</u>	<u>DATE</u>	<u>COUNTRY</u>	<u>CLASS</u>	<u>SUBCLASS</u>	<u>TRANSLATION YES</u>
-------------------------------	----------------------------	-------------	----------------	--------------	-----------------	----------------------------

OTHER REFERENCES**(INCLUDING AUTHOR, TITLE DATE, PERTINENT PAGES, ETC.)**

*EXAMINER
INITIALS

1. Ament, Ch. and Hofer, E.P., (2000) A fuzzy logical model of fracture healing. Journal of Biomechanics,

32:961-968

2. Amprino, R. and Engström, A. (1952) Studies on X-ray absorption and diffraction of bone tissue. Acta

Anat , 15, 1-22

3. Antman, S. (1995) Nonlinear Problems of Elasticity. Springer. New York

4. Ascenzi, M.-G. (2000) National Science Foundation grant description

5. Ascenzi, M.-G., Benvenuti, A., and Ascenzi, A. (2000) Single osteon micromechanical testing. In:

Mechanical testing of bone (An Y. and Draughn R. eds), CRC Press, Boca Raton, Florida

6. Ascenzi, M.-G. (1999a) Evidence of macroscopic prestress in human femoral shaft, Abstracts of the

XVIIth conference of the International Society of Biomechanics, Calgary

7. Ascenzi, M.-G. (1999b) A first estimation of prestress in so-called circularly fibered osteonic lamellae,

J. Biomech., 32, 935

RECEIVED

NOV 20 2002

TECH CENTER 2100/2900

RECEIVED

NOV 19 2002

LIST OF REFERENCES CITED BY APPLICANT

(Use Several Sheets if Necessary)

Technology Center 2100

DOCKET NO.: 3272/1H629US2 SERIAL NO: 09/981,684
APPLICANT: ASCENZI, Maria-Grazia FILING DATE: October 17, 2001
CONFIRMATION NO: 6620

***EXAMINER
INITIALS**

8. Ascenzi, M.-G. (1998a) A first estimate of prestress in so-called circularly fibered osteonic lamellae, Abstracts of the 11th conference of the European Society of Biomechanics, J. Biomech., 31, Suppl. I, 22.
9. Ascenzi, A., Benvenuti, A., Bigi, A., Foresti, E., Koch, M.H.J., Mango, F., Ripamonti, A., and Roveri, N. (1998) X-ray diffraction on cyclically loaded osteons. Calc. Tissue Int., 62:266-273
10. Ascenzi, A., Ascenzi M. G., Benvenuti, A., and Mango, F. (1997) Pinching in longitudinal and alternate osteons during cyclic loading. J. Biomechanics, 30, 689-695
11. Ascenzi, A., Baschieri P., and Benvenuti, A. (1994) The torsional properties of single selected osteons. J. Biomech., 27, 875-884
12. Ascenzi, A., Baschieri P., and Benvenuti, A. (1990) The bending properties of single osteons. J. Biomech., 23, 763-771
13. Ascenzi, A. (1988) The micromechanics versus the macromechanics of cortical bone - A comprehensive presentation. J. Biomech. Eng., 110, 357-363
14. Ascenzi, A., Boyde, A., Portigliatti-Barbos, M. and Carando, S. (1987a) Micro-biomechanics vs Macrobiomechanics in cortical bone. A micromechanical investigation of femurs deformed by bending. J. Biomech., 20, 1045-1053
15. Ascenzi, A., et al., (1986) Relationship between mechanical properties and structure in Secondary bone, Connective Tissue Research, 15:73-76
16. Ascenzi, A., Benvenuti, A., Mango, F. and Simili, R. (1985) Mechanical hysteresis loops from single osteons: Technical devices and preliminary results, J. Biomech., 18, 391-398

LIST OF REFERENCES CITED BY APPLICANT

(Use Several Sheets if Necessary)

DOCKET NO.: 3272/1H629US2 SERIAL NO: 09/981,684
APPLICANT: ASCENZI, Maria-Grazia FILING DATE: October 17, 2001
CONFIRMATION NO: 6620

***EXAMINER
INITIALS**

17. Ascenzi, A. and Bonucci, E. (1972) The shearing properties of single osteons. Anat. Rec., 172, 499-510

18. Ascenzi, A. and Bonucci, E. (1968) The compressive properties of single osteons. Anat. Rec., 161,

377-392

19. Ascenzi, A. and Bonucci, E. (1967) The tensile properties of single osteons. Anat. Rec., 158, 375-386

20. Ascenzi, A., et al., (1967) An Electron Microscope Study on Primary Periosteal Bone. J. Ultr. Research,

18:605-618

21. Ascenzi, A. and Bell, G.H., (1956) Bone as a mechanical engineering problem. In: The Biochemistry

and Physiology of Bone (Bourne G. H. ed) Academic Press, New York

22. Boyde, A., Bianco, P., Portigliatti-Barbos, M. and Ascenzi, A. (1984) Collagen Orientation in compact

bone: 1. A new method for the determination of the proportion of collagen parallel to the plane of compact bone sections,

Metab. Bone Dis. & Rel. Res., 5, 299-307.

23. Burr, D.B., Schaffler, M.B. and Frederickson, R.G. (1988) Composition of the cement line and its

possible mechanical role as a local interface in human compact bone. J. Biomech., 21, 939-945

24. Caler, W.E. and Carter, D.R. (1989) Bone creep-fatigue damage accumulation. J. Biomech., 22,

625-635

25. Carter, D.R., Caler, W.E., Spengler, D. M., and Frankel, V. H. (1981), Fatigue behavior of adult cortical

bone: The influence of mean strain and strain range., Acta Orthop. Scand., 52, 481-490

26. Carter, D.R. and Spengler, D.M. (1978) Mechanical properties and composition of cortical bone. Clin.

Orthop., 135,192-217

LIST OF REFERENCES CITED BY APPLICANT

(Use Several Sheets if Necessary)

DOCKET NO.: 3272/1H629US2 SERIAL NO: 09/981,684
APPLICANT: ASCENZI, Maria-Grazia FILING DATE: October 17, 2001
CONFIRMATION NO: 6620

***EXAMINER
INITIALS**

27. Carter, D.R. and Hayes, W.C. (1977) Compact bone fatigue damage - I. Residual strength and stiffness. J. Biomech., 10, 325-337.
28. Carter, D.R. and Hayes, W.C. (1976) Fatigue life of compact bone - I. Effects of stress amplitude, temperature and density. J. Biomech., 9, 27-34.
29. Carter, D.R., Hayes, W.C. and Schurman, D.J. (1976) Fatigue life of compact bone - II Effects of microstructure and density. J. Biomech., 9, 211-218.
30. Cook, J. and Gordon, J. E. (1964) A mechanism for the control of crack propagation in all brittle systems. Proc. R. Soc. Lond., Ser. A, 282, 508-520.
31. Couteau, B., Payan, Y., Lavallée, S. (2000) The mesh-matching algorithm: an automatic 3D mesh generator for finite element structures. J. Biomech., 33, 1005-1009.
32. Crolet J.-M., Aoubiza, B. and Meunier, A. (1993) Compact bone: numerical simulation of mechanical characteristics. J. Biomech., 26, 677-687.
33. Currey, J.D. (1964) Three analogies to explain the mechanical properties of bone. Biorheology, 2:1-10
34. Currey, J.D. (1959) Differences in tensile strength of bone of different histological types. J. Anat., 93, 87-95.
35. Evans, P. (1978) Relations between torsion properties and histology of adult human compact bone. J. Biomech., 11, 157-165
36. Evans, F.G. and Vincentelli, R. (1969) Relation of collagen fiber orientation to some mechanical properties of human cortical bone. J. Biomech., 2, 63-71

LIST OF REFERENCES CITED BY APPLICANT

(Use Several Sheets if Necessary)

DOCKET NO.: 3272/1H629US2 SERIAL NO: 09/981,684
APPLICANT: ASCENZI, Maria-Grazia FILING DATE: October 17, 2001
CONFIRMATION NO: 6620

***EXAMINER
INITIALS**

37. Frasca, P., Harper, R. and Katz, J. (1981) Strain and frequency dependence of shear storage modulus for human single osteons and cortical bone microsamples-size and hydration effects. J. Biomech, 14, 679-690
38. Frasca, P., Harper, R. and Katz, J. (1977) Collagen fiber orientation in human secondary osteons. Acta Anat., 98, 1-13.
39. Gebhardt, W., (1905) Ueber funktionell wichtige Anordnungsweisen der feineren und gr`beren Bauelemente des Wirbeltierknochens. II. Spezieller Teil. I. Der Bau der Haverssohen Lamellensysteme und seine funktionelle Bedeutung. Arch. Entwickl. Mech Org., 20, 187-3220
40. Giraud-Guille, M. M. (1988) Twisted plywood architecture of collagen fibrils in human compact bone osteons. Calc. Tissue Int., 42, 167-180.
41. Gupta, V., and Bergström, J.S. (1998) Compressive failure of rocks by shear faulting. J. of Geoph. Res. 103, 23, 875-23,895.
42. Hart, R.T., et al., (1992) Modeling the biomechanics of the mandible: a three-dimensional finite element study. J. Biomechanics, 25(3):261-286
43. Hert J., Fiala P. and Petrtyl M. (1994) Osteon orientation of the diaphysis of the long bones in man. Bone, 15, 269-277.
44. Hayes, W. and Carter, D. (1979) Biomechanics of Bone. In: Skeleton Research: An Experimental Approach (D. Simmons and A. Kunin, eds.), Academic Press Inc., New York, 1, 263-299.

LIST OF REFERENCES CITED BY APPLICANT

(Use Several Sheets if Necessary)

DOCKET NO.: 3272/1H629US2 SERIAL NO: 09/981,684
APPLICANT: ASCENZI, Maria-Grazia FILING DATE: October 17, 2001
CONFIRMATION NO: 6620

***EXAMINER
INITIALS**

45. Höhling, H.J., Barckhaus, R.H., Krefting, E.R., Althoff, J. and Quint, P. (1990) Collagen mineralization: aspects of the structural relationship between collagen and apatite cristallites. In: Ultrastructure of Skeletal Tissues: Bone and Cartilage in Health and Disease (E. Bonucci and P.M. Morra, eds.), Kluwer Academic Publishers, Boston, 41-62.
46. Huja, S.S., Hasan, M.S., Pidaparti, R., Turner, C.H., Garetto, L.P. and Burr, D. (1999) Development of a fluorescent light technique for evaluating microdamage in bone subjected to fatigue loading. J. Biomech., 32, 1243-1249.
47. Jepsen, K. J. and Davy, D.T. (1997) Comparison of damage accumulation measures in human cortical bone. J. Biomech., 30, 891-894.
48. Jepsen, K. J., Davy, D.T. and Krzypow, D. J. (1999) The role of the lamellar interface during torsional yielding of human cortical bone. J. Biomech., 32, 303-310.
49. Katz, J. L. and Meunier, A. (1987) The elastic anisotropy of bone. J. Biomech., 20, 1063-1070.
50. Katz, J. L. and Ukraincik, K. (1971) On the anisotropic elastic properties of hydroxyapatite. J. Biomech., 4, 221-227.
51. Kleerekoper, M., Villanueva, A. R., Stanciu, J., et al. (1985) The role of three-dimensional trabecular microstructure in the pathogenesis of vertebral compression fractures. Calc. Tissue. Int., 37, 594-597.
52. Koch, J. C. (1917) The laws of bone architecture. Am. J. Anat., 21, 177-293.
53. Lakes, R. (1995) On the torsional properties of single osteons, J. Biomech., 28, 1409-1410.
54. Mah, J. and Hatcher, D. (2000) Imaging trends and applications for the millenium. Orthod. Prod., 1, 14-18.

LIST OF REFERENCES CITED BY APPLICANT

(Use Several Sheets if Necessary)

RECEIVED

NOV 19 2002

DOCKET NO.: 3272/1H629US2
APPLICANT: ASCENZI, Maria-GraziaSERIAL NO: 09/981,684
FILING DATE: October 17, 2001
CONFIRMATION NO: 6620***EXAMINER
INITIALS**

55. Martens, M., van Audekercke, R., de Meester, P. and Mulier, J. (1980) The mechanical characteristics of the long bones of the lower extremity in torsional loading. J. Biomech., 13, 667-676.
56. Miller, G. and Piotrowski, G. (1974) A brief note on the variability of the torsional strength of paired bones. J. Biomechanics, 7, 247-248.
57. Moreland, M. (1980) Morphological effects of torsion applied to growing bone. J. Bone Jt. Surg., 62-B, 230-237.
58. Philipson, B. (1965) Composition of cement lines in bone. J. Histochem. Cytochem., 13, 270-281.
59. Pidaparti, R. and Burr D. (1992) Collagen fiber orientation and geometry effects on the mechanical properties of secondary osteons. J. Biomech., 25, 869-880.
60. Piekarski, K. (1970) Fracture of bone. J. of Appl. Physics, 41, 215-223.
61. Portigliatti-Barbos, M., Bianco, P. and Ascenzi, A. (1983) Distribution of osteonic and interstitial components in the human femoral shaft with reference to structure, calcification, and mechanical properties. Acta Anat., 115, 178-186.
62. Portigliatti-Barbos, M., Bianco, P., Ascenzi, A. and Boyde, A. (1984) Collagen orientation in compact bone: II. Distribution of lamellae in the whole of the human femoral shaft with reference to its mechanical properties. Metab. Bone Dis. & Rel. Res., 5, 309-315.
63. Portigliatti-Barbos, M., Carando, S., Ascenzi, A. and Boyde, A. (1987) On the structural symmetry of human femurs, Bone, 8, 165-169.

LIST OF REFERENCES CITED BY APPLICANT

(Use Several Sheets if Necessary)

DOCKET NO.: 3272/1H629US2 SERIAL NO: 09/981,684
APPLICANT: ASCENZI, Maria-Grazia FILING DATE: October 17, 2001
CONFIRMATION NO: 6620

***EXAMINER
INITIALS**

64. Rho, J.Y., Zioupos, P., Currey, J.D., and Pharr, G. M. (1999) Variations in the individual thick lamellar properties within osteons by nanoindentation, *Bone*, 25, 295-300.
65. Riggs, C. M., Lanyon, L. E., and Boyde, A. (1993a) Functional associations between collagen fibre orientation and locomotor strain direction in cortical bone of the equine radius, *Anat. Embryol.*, 187, 231-238.
66. Riggs, C. M., Vaughan, L. C., Evans, G. P., Lanyon, L. E. and Boyde, A. (1993b) Mechanical implications of collagen fibre orientation in cortical bone of the equine radius, *Anat. Embryol.*, 187, 239-248.
67. Sasaki N. (2000) Viscoelastic properties of bone and testing methods. In: *Mechanical testing of bone* (An Y. and Draughn R. eds), CRC Press, Boca Raton, Florida.
68. Schaffler, M., Burr, D. B. and Frederickson, R. G. (1987) Morphology of the osteonal cement line in human bone. *Anat. Rec.*, 217, 223-228.
69. Shiga, T., Ogawa, J., Shibata, A. and Shibuya, J. (1970) The dynamic properties of reinforced concrete frames. *Proceedings of the United States-Japan Seminar on Earthquake Engineering with emphasis on safety of school buildings*. September, 346-363.
70. Simkin, A., and Robin, G. (1974) Fracture formation in differing collagen fiber pattern of compact bone. *J. Biomech.*, 7, 183-188.

LIST OF REFERENCES CITED BY APPLICANT

(Use Several Sheets if Necessary)

DOCKET NO.: 3272/1H629US2 SERIAL NO: 09/981,684
APPLICANT: ASCENZI, Maria-Grazia FILING DATE: October 17, 2001
CONFIRMATION NO: 6620

* EXAMINER
INITIALS

71. Vincentelli, R. and Evans, F. G. (1971) Relations among mechanical properties, collagen fibers, and calcification in adult human cortical bone. J. Biomech., 4, 193-201.

72. Ziv, V., Wagner, M. D., and Weiner, S. (1996) Microstructure-microhardness relations in parallel-fibered and lamellar bone. Bone, 18, 417-428.

73. Zysset, P.K., Guo X.E., Hoffler C.E., Moore K.E., and Goldstein S. (1999) Elastic modulus and hardness of cortical and trabecular bone lamellae measured by nanoindentation in the human femur. J. Biomech., 32, 1005-1012.

EXAMINER: _____

DATE CONSIDERED: _____

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.